



**EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2013. Scientific Opinion on the substantiation of a health claim related to riboflavin (vitamin B2) and contribution to normal energy-yielding metabolism pursuant to Article 14 of Regulation (EC) No 1924/2006**

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## SCIENTIFIC OPINION

### **Scientific Opinion on the substantiation of a health claim related to riboflavin (vitamin B2) and contribution to normal energy-yielding metabolism pursuant to Article 14 of Regulation (EC) No 1924/2006<sup>1</sup>**

**EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)<sup>2, 3</sup>**

European Food Safety Authority (EFSA), Parma, Italy

#### **ABSTRACT**

Following an application from Specialised Nutrition Europe (formerly IDACE), submitted pursuant to Article 14 of Regulation (EC) No 1924/2006 via the Competent Authority of France, the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) was asked to deliver an opinion on the scientific substantiation of a health claim related to riboflavin (vitamin B2) and contribution to normal energy-yielding metabolism. The food constituent, riboflavin, which is the subject of the health claim, is sufficiently characterised. Contribution to normal energy-yielding metabolism is a beneficial physiological effect for infants and young children. A claim on riboflavin and contribution to normal energy-yielding metabolism in the general population has already been assessed with a favourable outcome. The Panel notes that the role of riboflavin on normal energy-yielding metabolism applies to all ages, including infants and young children (from birth to three years). The Panel concludes that a cause and effect relationship has been established between the dietary intake of riboflavin and contribution to normal energy-yielding metabolism.

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#### **KEY WORDS**

riboflavin, vitamin B2, infants, children, energy-yielding metabolism, health claims

<sup>1</sup> On request from the Competent Authority of France following an application by Specialised Nutrition Europe (formerly IDACE), Question No EFSA-Q-2008-184, adopted on 09 October 2013.

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## SUMMARY

Following an application from Specialised Nutrition Europe (formerly IDACE), submitted for authorisation of a health claim pursuant to Article 14 of Regulation (EC) No 1924/2006 via the Competent Authority of France, the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) was asked to deliver an opinion on the scientific substantiation of a health claim related to riboflavin (vitamin B2) and contribution to normal energy-yielding metabolism.

The scope of the application was proposed to fall under a health claim referring to children's development and health.

The food constituent that is the subject of the health claim is riboflavin (vitamin B2), which is an essential nutrient and is measurable in foods by established methods. The Panel considers that riboflavin is sufficiently characterised.

The claimed effect proposed by the applicant is “has an important role as a coenzyme in energy-yielding metabolism”. The target population proposed by the applicant is infants and young children from birth to three years of age. The Panel considers that contribution to normal energy-yielding metabolism is a beneficial physiological effect for infants and young children.

A claim on riboflavin and contribution to normal energy-yielding metabolism in the general population has already been assessed with a favourable outcome. The conclusion of the Panel was based on the well-established role of riboflavin in energy-yielding metabolism as shown by the evidence provided by consensus opinions/reports from authoritative bodies and reviews.

The Panel notes that the role of riboflavin on normal energy-yielding metabolism applies to all ages, including infants and young children (from birth to three years).

The Panel concludes that a cause and effect relationship has been established between the dietary intake of riboflavin and contribution to normal energy-yielding metabolism.

The following wording reflects the scientific evidence: “Riboflavin contributes to normal energy-yielding metabolism”.

The Panel considers that in order to bear the claim, follow-on formulae should comply with the criteria of composition of follow-on formulae as laid down in Directive 2006/141/EC; nutritionally complete foods for special medical purposes intended for use by infants and nutritionally complete foods for special medical purposes other than those intended for use by infants should comply with the criteria of composition of these foods as laid down in Directive 1999/21/EC; processed cereal-based foods for infants and young children should comply with the criteria of composition of these foods as laid down in Directive 2006/125/EC; other foodstuffs intended for infants and young children should provide at least 15 % of the reference values for nutrition labelling for foods intended for infants and young children as laid down in Directive 2006/141/EC. The target population is infants and children up to three years. No Tolerable Upper Intake Level has been established for riboflavin in this age group.

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## BACKGROUND

Regulation (EC) No 1924/2006<sup>4</sup> harmonises the provisions that relate to nutrition and health claims, and establishes rules governing the Community authorisation of health claims made on foods. As a rule, health claims are prohibited unless they comply with the general and specific requirements of this Regulation, are authorised in accordance with this Regulation, and are included in the lists of authorised claims provided for in Articles 13 and 14 thereof. In particular, Articles 14 to 17 of this Regulation lay down provisions for the authorisation and subsequent inclusion of reduction of disease risk claims and claims referring to children's development and health in a Community list of permitted claims.

According to Article 15 of this Regulation, an application for authorisation shall be submitted by the applicant to the national competent authority of a Member State, which will make the application and any supplementary information supplied by the applicant available to the European Food Safety Authority (EFSA).

## STEPS TAKEN BY EFSA

- The application was received on 14/02/2008.
- The scope of the application was proposed to fall under a health claim referring to children's development and health.
- On 26/03/2008, during the validation process of the application, EFSA sent a request to the applicant to provide missing information.
- On 26/06/2013, EFSA received the missing information as submitted by the applicant.
- The scientific evaluation procedure started on 16/07/2013.
- During its meeting on 09/10/2013, the NDA Panel, having evaluated the data submitted, adopted an opinion on the scientific substantiation of a health claim related to riboflavin (vitamin B2) and contribution to normal energy-yielding metabolism.

## TERMS OF REFERENCE

EFSA is requested to evaluate the scientific data submitted by the applicant in accordance with Article 16 of Regulation (EC) No 1924/2006. On the basis of that evaluation, EFSA will issue an opinion on the scientific substantiation of a health claim related to: riboflavin and contribution to normal energy-yielding metabolism.

## EFSA DISCLAIMER

The present opinion does not constitute, and cannot be construed as, an authorisation for the marketing of riboflavin, a positive assessment of its safety, nor a decision on whether riboflavin is, or is not, classified as a foodstuff. It should be noted that such an assessment is not foreseen in the framework of Regulation (EC) No 1924/2006.

It should also be highlighted that the scope, the proposed wording of the claim, and the conditions of use as proposed by the applicant may be subject to changes, pending the outcome of the authorisation procedure foreseen in Article 17 of Regulation (EC) No 1924/2006.

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<sup>4</sup> Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods. OJ L 404, 30.12.2006, p. 9–25.

## **INFORMATION PROVIDED BY THE APPLICANT**

**Applicant's name and address:** Specialised Nutrition Europe (formerly IDACE), 9-31 Avenue des Nerviens, 1040 Brussels, Belgium.

### **Food/constituent as stated by the applicant**

According to the applicant, the food constituent for which the claim is made is vitamin B2 (riboflavin).

### **Health relationship as claimed by the applicant**

According to the applicant, riboflavin has an important role as a coenzyme in energy-yielding metabolism acting as an electron carrier in a wide variety of oxidation and reduction reactions that are central to many metabolic processes, including the mitochondrial electron transport chain, fatty acid and amino acid oxidation, and the citric acid cycle.

### **Wording of the health claim as proposed by the applicant**

The applicant has proposed the following wording for the health claim: "vitamin B2 (riboflavin) is needed to release energy from foods".

As equivalent alternative wordings, the applicant has also proposed: "vitamin B2 (riboflavin) contributes to the normal release of energy from foods/helps convert food to energy/is needed for the release of energy from proteins, fats and carbohydrates/helps in the metabolism of carbohydrates, proteins and fats".

### **Specific conditions of use as proposed by the applicant**

According to the applicant, the target population is infants and young children from birth to three years of age.

According to the applicant, the quantity needed to achieve the claimed effect is:

- For follow-on formulae, the content in riboflavin should be within the range set in Directive 2006/141/EC.
- For dietary foods for special medical purposes, the content in riboflavin should be within the range set in Directive 1999/21/EC.
- For processed cereal-based foods and baby foods, the content in riboflavin should be within the range set in Directive 2006/125/EC.
- For processed cereal-based foods and baby foods, the content in riboflavin should reach at least 15 % of the Nutrient Reference Values set in Directive 2006/125/EC, i.e. 15 % of 800 µg (120 µg) per 100 g or 100 ml or per serving, as reconstituted.
- For foods intended for infants and young children other than follow-on formulae, processed cereal-based foods and baby foods, the content in riboflavin should reach at least 15 % of the Nutrient Reference Values set in Directive 2006/141/EC, i.e. 15 % of 700 µg (105 µg) per 100 ml product ready for use.

## ASSESSMENT

### 1. Characterisation of the food/constituent

The food constituent that is the subject of the health claim is riboflavin (vitamin B2), which is an essential nutrient and is measurable in foods by established methods.

Riboflavin occurs naturally in foods and is authorised for addition to foods (Annex I of Regulation (EC) No 1925/2006<sup>5</sup>, Annex I of Directive 2002/46/EC<sup>6</sup>, Annex III of Directive 2006/141/EC<sup>7</sup>, Annex IV of Directive 2006/125/EC<sup>8</sup>, Directive 2001/15/EC<sup>9</sup>). This evaluation applies to riboflavin naturally present in foods and those forms authorised for addition to foods (Annex II of Regulation (EC) No 1925/2006, Annex II of Directive 2002/46/EC, Annex III of Directive 2006/141/EC, Annex IV of Directive 2006/125/EC, Directive 2001/15/EC).

The Panel considers that the food constituent, riboflavin, which is the subject of the health claim, is sufficiently characterised.

### 2. Relevance of the claimed effect to human health

The claimed effect proposed by the applicant is “has an important role as a coenzyme in energy-yielding metabolism”. The target population proposed by the applicant is infants and young children from birth to three years of age.

The Panel considers that contribution to normal energy-yielding metabolism is a beneficial physiological effect for infants and young children.

### 3. Scientific substantiation of the claimed effect

The applicant performed a literature search in PubMed, which was limited to “humans” and “review”, using “B vitamin [ti]” AND “mitochondrial” AND “metabolism” as search terms, without specifying which period was covered. Two review publications on the role of B vitamins on mitochondrial function were retrieved through this literature search (Depeint et al., 2006a, b). The applicant also identified some opinions/reports from authoritative bodies as being pertinent to the health claim (IoM, 1998; SCF, 2000; FAO/WHO, 2001; EVM, 2002).

Riboflavin is a precursor of certain essential coenzymes such as flavin mononucleotide (FMN) and flavin-adenine dinucleotide (FAD), which participate in oxidation and reduction reactions of many metabolic processes, including the mitochondrial electron transport chain, fatty acid and amino acid oxidation, and the citric acid cycle (Bender, 2003; Rivlin, 2006).

The Panel has already assessed a claim on riboflavin and contribution to normal energy-yielding metabolism with a favourable outcome (EFSA NDA Panel, 2010). The target population was the general population.

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<sup>5</sup> Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods. OJ L 404, 30.12.2006, p. 26–38.

<sup>6</sup> Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements. OJ L 183, 12.7.2002, p. 51–57.

<sup>7</sup> Commission Directive 2006/141/EC of 22 December 2006 on infant formulae and follow-on formulae and amending Directive 1999/21/EC Text with EEA relevance. OJ L 401, 30.12.2006, p. 1–33.

<sup>8</sup> Commission Directive 2006/125/EC of 5 December 2006 on processed cereal-based foods and baby foods for infants and young children. OJ L 339, 6.12.2006, p. 16–35.

<sup>9</sup> Commission Directive 2001/15/EC of 15 February 2001 on substances that may be added for specific nutritional purposes in foods for particular nutritional uses. OJ L 52, 22.2.2001, p. 19–25.

The conclusion of the Panel was based on the well-established role of riboflavin in energy-yielding metabolism as shown by the evidence provided by consensus opinions/reports from authoritative bodies and reviews (IoM, 1998; SCF, 2000; EVM, 2002; JHCI, 2003; Bates, 2005).

The Panel notes that the role of riboflavin in normal energy-yielding metabolism applies to all ages, including infants and young children (from birth to three years).

The Panel concludes that a cause and effect relationship has been established between the dietary intake of riboflavin and contribution to normal energy-yielding metabolism.

#### **4. Panel's comments on the proposed wording**

The Panel considers that the following wording reflects the scientific evidence: "Riboflavin contributes to normal energy-yielding metabolism".

#### **5. Conditions and restrictions of use**

The Panel considers that in order to bear the claim:

- follow-on formulae should comply with the criteria of composition of follow-on formulae as laid down in Directive 2006/141/EC;
- nutritionally complete foods for special medical purposes intended for use by infants and nutritionally complete foods for special medical purposes other than those intended for use by infants should comply with the criteria of composition of these foods as laid down in Directive 1999/21/EC<sup>10</sup>;
- processed cereal-based foods for infants and young children should comply with the criteria of composition of these foods as laid down in Directive 2006/125/EC;
- other foodstuffs intended for infants and young children should provide at least 15 % of the reference values for nutrition labelling for foods intended for infants and young children as laid down in Directive 2006/141/EC.

Such amounts can be easily consumed as part of a balanced diet. The target population is infants and children up to three years. No Tolerable Upper Intake Level (UL) has been established for riboflavin in this age group.

### **CONCLUSIONS**

On the basis of the data presented, the Panel concludes that:

- The food constituent, riboflavin, which is the subject of the health claim, is sufficiently characterised.
- The claimed effect proposed by the applicant is "has an important role as a coenzyme in energy-yielding metabolism". The target population proposed by the applicant is infants and young children from birth to three years of age. Contribution to normal energy-yielding metabolism is a beneficial physiological effect for infants and young children.

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<sup>10</sup> Commission Directive 1999/21/EC of 25 March 1999 on dietary foods for special medical purposes. OJ L 91, 7.4.1999, p. 29–36.



- A cause and effect relationship has been established between the dietary intake of riboflavin and contribution to normal energy-yielding metabolism.
- The following wording reflects the scientific evidence: “Riboflavin contributes to normal energy-yielding metabolism”.
- In order to bear the claim, follow-on formulae should comply with the criteria of composition of follow-on formulae as laid down in Directive 2006/141/EC; nutritionally complete foods for special medical purposes intended for use by infants and nutritionally complete foods for special medical purposes other than those intended for use by infants should comply with the criteria of composition of these foods as laid down in Directive 1999/21/EC; processed cereal-based foods for infants and young children should comply with the criteria of composition of these foods as laid down in Directive 2006/125/EC; other foodstuffs intended for infants and young children should provide at least 15 % of the reference values for nutrition labelling for foods intended for infants and young children as laid down in Directive 2006/141/EC. The target population is infants and children up to three years. No UL has been established for riboflavin in this age group.

## DOCUMENTATION PROVIDED TO EFSA

Health claim application on riboflavin (vitamin B2) and contribution to normal energy-yielding metabolism pursuant to Article 14 of Regulation (EC) No 1924/2006 (Claim serial No: 0104\_FR). February 2008. Submitted by Specialised Nutrition Europe (formerly IDACE).

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## **ABBREVIATIONS**

UL	Tolerable Upper Intake Level
FMN	Flavin Mononucleotide
FAD	Flavin-adenine Dinucleotide